

ARNOLD & PORTER

202.942.5000
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206



December 12, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Application No. 10/656,093
Filed: September 5, 2003
Title: **Inotropic and Diuretic Effects of GLP-1 and
GLP-1 Agonists**
Applicants: Andrew A. YOUNG *et al.*
Atty. Docket: 18528.632

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. an Information Disclosure Statement and PTO-1449 form (3 pages); and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

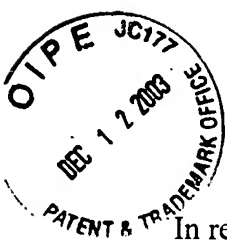
In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 18528.632. A duplicate copy of this letter is enclosed.

Respectfully submitted,

A handwritten signature in cursive script that reads "Milan M. Vinnola".

David R. Marsh (Reg. No. 41,408)
Milan M. Vinnola (Reg. No. 45,979)

Attachments



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Andrew A. YOUNG *et al.*

Group Art Unit: To Be Assigned

Appln. No.: 10/656,093

Examiner: To Be Assigned

Filed: September 5, 2003

Atty. Docket: 18528.632

For: **Inotropic and Diuretic Effects of
GLP-1 and GLP-1 Agonists**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the references listed on the attached Form PTO-1449. These references were previously considered in an earlier filed application, U.S. Patent Application Serial No. 09/622,105, filed September 9, 2000, upon which the instant application relies on for an earlier effective filing date under 35 U.S.C. 120. Applicants further submit that the references filed in the Information Disclosure Statement in the earlier application complied with 37 C.F.R. 1.98(a)-(c). Accordingly, Applicants submit that under 37 C.F.R. 1.98(d)(1)-(2), copies of the listed references need not be provided. However, the Examiner is requested to notify the Applicants should he/she require a copy of any or all of the listed references.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Milan M. Vinnola". The signature is fluid and cursive, with the first name "Milan" and last name "Vinnola" clearly distinguishable.

David R. Marsh (Reg. No. 41,408)
Milan M. Vinnola (Reg. No. 45,979)

Date: December 12, 2003

ARNOLD & PORTER
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18528.632

APPLICATION NO.

10/656,093

APPLICANTS

Andrew A. YOUNG *et al.*

FILING DATE

September 5, 2003

GROUP

To Be Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	5,424,286	6/1995	Eng			
	AB1	5,512,549	4/1996	Chen			
	AC1	5,545,618	8/1996	Buckley			
	AD1	5,574,008	11/1996	Johnson			
	AE1	5,846,937	12/1998	Drucker			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AF1	WO 98/05351	2/1998	PCT			Yes No
	AG1	WO 99/07404	2/1999	PCT			Yes No

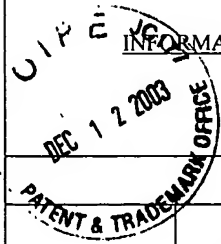
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AH1	Barragán <i>et al.</i> , "Interactions of exendin-(9-39) with the effects of glucagon-like peptide-1-(7-36) amide and of exendin-4 on arterial blood pressure and heart rate in rats", <u>Regulatory Peptides</u> , 67:63-68 (1996)
	AI1	Bhavsar <i>et al.</i> , "Inhibition of gastric emptying and of food intake appear to be independently controlled in rodents", <u>Soc. Neurosci. Abstr.</u> , 21:460 (188.8) (1995)
	AJ1	D'Alessio <i>et al.</i> , "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons", <u>J. Clin. Invest.</u> , 97(1):133-138 (1996)
	AK1	Edwards <i>et al.</i> , "Cardiovascular and Pancreatic Endocrine Responses to Glucagon-Like Peptide-1(7-36) Amide in the Conscious Calf", <u>Exp. Physiol.</u> , 82:709-716 (1997)
	AL1	Eissele <i>et al.</i> , "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-Like Peptide-1 (GLP-1) Amide", <u>Life Sci.</u> , 55(8):629-634 (1994)
	AM1	Eng <i>et al.</i> , "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom", <u>J. Biol. Chem.</u> , 265(33):20259-20262 (1990)
	AN1	Eng <i>et al.</i> , "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom", <u>J. Biol. Chem.</u> , 267(11):7402-7405 (1992)
	AO1	Fehmann <i>et al.</i> , "Stable Expression of the Rat GLP-1 Receptor in CHO Cells: Activation and Binding Characteristics Utilizing GLP-1(7-36)-Amide, Oxyntomodulin, Exendin-4, and Exendin(9-39)", <u>Peptides</u> , 15(3):453-456 (1994)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

 FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO.	APPLICATION NO.
		18528.632	10/656,093
		APPLICANTS	
		Andrew A. YOUNG <i>et al.</i>	
		FILING DATE	GROUP
		September 5, 2003	To Be Assigned
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AA2	Ferguson <i>et al.</i> , "Cell-Surface Anchoring of Proteins via Glycosylphosphatidylinositol Structures", <u>Annu. Rev. Biochem.</u> , 57:285-320 (1988)	
	AB2	Göke <i>et al.</i> , "Exendin-4 is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β -Cells", <u>J. Biol. Chem.</u> , 268(26):19650-19655 (1993)	
	AC2	Knudsen <i>et al.</i> , "Potent Derivatives of Glucagon-like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration", <u>J. Med. Chem.</u> , 43:1664-1669 (2000)	
	AD2	Kolligs <i>et al.</i> , "Reduction of the Incretin Effect in Rats by the Glucagon-Like Peptide 1 Receptor Antagonist Exendin (9-39) Amide", <u>Diabetes</u> , 44:16-19 (1995)	
	AE2	Malhotra <i>et al.</i> , "Exendin-4, a new peptide from <i>Heloderma suspectum</i> venom, potentiates cholecystokinin-induced amylase release from rat pancreatic acini", <u>Regulatory Peptides</u> , 41:149-156 (1992)	
	AF2	Montrose-Rafizadeh <i>et al.</i> , "Structure-function Analysis of Exendin-4 / GLP-1 Analogs", <u>Diabetes</u> , 45(Suppl. 2):152A (1996)	
	AG2	O'Halloran <i>et al.</i> , "Glucagon-like peptide-1 (7-36)-NH ₂ : a physiological inhibitor of gastric acid secretion in man", <u>Journal of Endocrinology</u> , 126:169-173 (1990)	
	AH2	Ørskov <i>et al.</i> , "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects are Indistinguishable", <u>Diabetes</u> , 42:658-661 (1993)	
	AI2	Raufman <i>et al.</i> , "Exendin-3, a Novel Peptide from <i>Heloderma horridum</i> Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly Described Receptor on Dispersed Acini from Guinea Pig Pancreas", <u>J. Biol. Chem.</u> , 266(5):2897-2902 (1991)	
	AJ2	Raufman <i>et al.</i> , "Truncated Glucagon-like Peptide-1 Interacts with Exendin Receptors in Dispersed Acini from Guinea Pig Pancreas", <u>J. Biol. Chem.</u> , 267(30):21432-21437 (1992)	
	AK2	Schepp <i>et al.</i> , "Exendin-4 and exendin-(9-39)NH ₂ : agonist and antagonist, respectively, at the rat parietal cell receptor for glucagon-like peptide-1-(7-36)NH ₂ ", <u>Eur. J. Pharm.</u> , 269:183-191 (1994)	
	AL2	Schjoldager <i>et al.</i> , "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans", <u>Digestive Disease and Sciences</u> , 34(5):703-708 (1989)	
	AM2	Singh <i>et al.</i> , "Use of ¹²⁵ I-[Y ³⁹]exendin-4 to characterize exendin receptors on dispersed pancreatic acini and gastric chief cells from guinea pig", <u>Regulatory Peptides</u> , 53:47-59 (1994)	
EXAMINER			DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.			

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18528.632

APPLICATION NO.

10/656,093

APPLICANTS

Andrew A. YOUNG *et al.*

FILING DATE

September 5, 2003

GROUP

To Be Assigned

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AA3

Tang-Christensen *et al.*, "Central administration of GLP-1-(7-36) amide inhibits food and water intake in rats", Am. J. Physiol., 271:R848-R856 (1996)

AB3

Thorens *et al.*, "Expression cloning of the Pancreatic β cell receptor for the gluco-incretin hormone glucagon-like peptide 1", Proc. Natl. Acad. Sci. USA, 88:8641-8645 (1992)

AC3

Thorens *et al.*, "Cloning and Functional Expression of the Human Islet GLP-1 Receptor", Diabetes, 42:1678-1682 (1993)

AD3

Turton *et al.*, "A role for glucagon-like peptide-1 in the central regulation of feeding", Nature, 379:69-72 (1996)

AE3

Wang *et al.*, "Glucagon-like Peptide-1 is a Physiological Incretin in Rat", J. Clin. Invest., 95:417-421 (1995)

AF3

Wettergren *et al.*, "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man", Digestive Diseases and Sciences, 38(4):665-673 (1993)

AG3

Willms *et al.*, "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients", J. Clin. Endocrinol. Metab., 81(1):327-332 (1996)

AH3

Young *et al.*, "Preclinical Pharmacology of Pramlintide in the Rat: Comparisons with Human and Rat Amylin", Drug Development Research, 37:231-248 (1996)

AI3

AJ3

AK3

AL3

AM3

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.